DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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DRTech Corporation
% Mr. Choul-Woo Shin
Vice President
Suite No. 2, 3rd Floor, Dunchon-daero541beon-gil
Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807
REPUBLIC OF KOREA

January 15, 2015

Re: K142475
Trade/Device Name: EVS 4343
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 3, 2014
Received: December 5, 2014

Dear Mr. Shin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142475

Device Name
EVS 4343

Indications for Use *(Describe)*
The EVS 4343 Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

08/27/2014

2. Submitter's Information [21 CFR 807.92(a) (1)]

- Name of Sponsor: DRTECH Corporation
- Address: Suite No. 2, 3 Floor, 29, Dunchon-daero541beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do 462-807 Republic of Korea
- Contact Name: Choul-Woo Shin
  Telephone No. : + 82-31-784-8856
  Fax No. : + 82-31-784-8899
  Email Address : cwshin@drtech.co.kr
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

- Trade Name: EVS 4343
- Common Name: Digital Flat Panel X-ray Detector
- Classification Name: Stationary X-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892. 1680
- Product Code: MQB
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

- 510(k) Number: K091090
- Applicant: E-WOO TECHNOLIGY
- Trade Name: Xmaru1717
- Common Name: Digital Flat Panel X-ray Detector
- Classification Name: Stationary X-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892. 1680
- Product Code: MQB
- Device Class: II

5. Description of the Device [21 CFR 807.92(a) (4)]

The EVS 4343 is a wired/wireless flat-panel type digital X-ray detector that captures projection radiographic images in digital format within seconds, eliminating the need for an entire x-ray film or an image plate as an image capture medium. EVS 4343 differs from traditional X-ray systems in that, instead of exposing a film and chemically processing it to create a hard copy image, a device called a Detector is used to capture the image in electronic form.

EVS 4343 consists of main components such as SSU, USB Switch Box and other accessories (Tether Interface Cable, Access Point, Hand Switch, Generator Interface Cable, LAN Cable, Interface cable, AC Power Code).

6. Intended Use [21 CFR 807.92(a)(5)]

The Intended Use of the DRTECH EVS 4343 Digital X-ray detector is identical to that of the currently marketed and predicate device, E-Woo Technology Xmaru1717 (cleared in K091090, August 9, 2010) and is as follows:

The EVS 4343 Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Based on a technical feature comparison, the subject device was found to be similar to predicate devices with regard to detector technology (Indirect, CsI) which has the same pane size.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

<Device Comparison table>

Parameter	Subject Device	Predicate Device	Remark
510(k) Number	Unknown	K091090	-
Manufacturer	DRTECH Corporation	E-WOO TECHNOLOGY	-
Model Name	EVS 4343	Xmaru 1717	-
Common Name	Digital Flat Panel X-ray Detector		Same
Classification Name	Solid State X-ray Imager (Flat Panel/Digital Imager)		Same
Classification Panel	Radiology		Same
Classification Regulation	21 CFR 892.1680		Same
Product Code	MQB		Same
Device Class	Class II		Same

Intended Use		The EVS 4343 Digital X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. This device is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. This device is not intended for mammography applications	Xmaru1717 Digital Flat Panel X-ray Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	Same
Design	Panel Shape	Square Panel	Square Panel	Same
	Detector Size	17” X 17”	17” X 17”	Same
	Dimensions (W x L x H)	460(W)x460(L)x15(H)	497(W)×500(L)×45(H)	Similarity
	Pixel Pitch	140μm	143μm	Similarity
	Image Size	3,072 x 3,072	3,072 x 3,072	Same
Materials Scintillator		TFT –amorphous Silicon CsI (Indirect)	TFT –amorphous Silicon CsI (Indirect)	Same
Performance	DQE	34.7% (at 1.0lp/mm)	36.2% (at 1.0lp/mm)	Similarity
	MTF	64.3% (at 1.0lp/mm)	49.1% (at 1.0lp/mm)	Difference
	Resolution	3.6LP/mm	3.6LP/mm	Same
Anatomical Sites		General Radiography	General Radiography	Same
Power Supply		100~240V~, 50/60 Hz	100~240V~, 50/60 Hz	Same

When compared to the predicate device (K091090), the EVS 4343 presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Communication Method

There are no significant difference between the EVS 4343 and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

9. Summary of Non-Clinical Data

The non-clinical performance testing constrains that the main physical values for comparison of X-ray devices like DQE and MTF are basically equal or better than the predicate device ranging 64.3% (predicate 18.8%) for MTF at 1.0lp/mm and 34.7% (predicate 36.2%) for DQE at 1.0lp/mm.

The DRTECH EVS 4343 Digital X-ray detector complies with the following international and FDA-recognized consensus standards:

AAMI ANSI ES60601-1:	Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod)
IEC 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
ISO 14971:	Medical Devices - Application Of Risk Management To Medical Devices. (General I (QS/RM))
IEC 62220-1:	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
NEMA PS 3.1 - 3.20:	Digital Imaging and Communications in Medicine (DICOM) Set

10. Summary of Clinical Data

A single-blinded concurrence study according to CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices was conducted, and the study confirmed that the new x-ray detectors EVS 4343 provide images of equivalent diagnostic capability to the predicate device, the E-WOO TECHNOLOGY Xmaru1717, and its results demonstrate substantial equivalence.

11. Conclusion [21 CFR 807.92(b) (3)]

The DRTECH EVS 4343 Digital X-ray detector is substantially equivalent to the currently marketed and predicate device (E-WOO TECHNOLOGY Xmaru1717 K091090) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, AAMI ANSI ES60601-1, IEC 60601-1-2, ISO 14971, IEC 62220-1 and NEMA PS 3.1 - 3.20 and the clinical test, which complied with the requirements specified in the CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

The results of these tests demonstrate that DRTECH EVS 4343 Digital X-ray detector meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.